BESCHEINIGUNG ■ CERTIFICATION ■ ATTESTATION ■ CONSTANCIA ■ شهادة ■ BELGE

TÜV SÜD Akademie

Certification

TÜV SÜD Akademie hereby certifies, that

Mustafa Dinc

born on 04.12.1973 in Germany has participated in

Medical Device Regulation (MDR) in Detail

training course on 27.06.2017 in Baar.

Course content:
- Fundamentals and content of the new Medical Device Regulation (MDR)
- Classification / reclassification of products
- Non-medical devices within the scope of the Medical Device Regulation (MDR)
- Common Technical Specifications
- The "new essential requirements"
- The requirements for technical documentation
- Post Market Surveillance
- Scrutiny process
- Validity of conformity assessment and certificates, transitional periods
- Requirements on the different actors such as:
  - Manufacturers
  - Importers
  - EU Representatives
  - Distributors and service partners
- Role of the person responsible for Regulatory Compliance
- Eudamed database
- UDI (Unique Device Identification)

Duration of the training: 8 Teaching Units

Baar, 27.06.2017

Jörg Schemat, Geschäftsführer

Susanne Lamprecht

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